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510(k) Summary of Safety and Effectiveness

September 20, 2003

Submitter

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 530-7500
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Contact: Dave Klementowski, Senior Manager, Regulatory Affairs at 315-685-4133 or if he is not available, Chris Letscher at 503-530-7389.

Device Name:

Trade Name: VSM (vital signs monitor), Propaq LT
Common Name: Cardiac Monitor
Classification Name: Cardiac Monitor (Reference, 21CFR870.2300), NIBP measurement system (Reference 21CFR870.1130, April 1, 2003). The VSM model Propaq LT 802 Series also contain a Pulse Oximetry (SpO_2) channel (Reference, 21CFR870.2700, April 1, 2003) April 1, 2003), and radio frequency physiologic signal transmitter (Reference, 870.2910, April 2003)

Classification: Class II

Predicate Devices

The predicate devices for the Propaq LT 802 Series monitors are:

- Welch Allyn Protocol, Propaq Encore Model 2XX Series, K951246, K012451,
- Welch Allyn Protocol, VSM Model 5300, KO21681, K031740
- Welch Allyn Protocol, Micropaq Model 402/404, K002725
- Nellcor Puritan Bennett Pulse Oximeter Model N-550, K021090

Device Description

The Propaq LT 802 Series of monitors are small, lightweight patient monitoring devices intended to be used by clinicians and medically qualified personnel for monitoring of noninvasive blood pressure, pulse rate, ECG, noninvasive functional oxygen saturation of arteriolar hemoglobin (SpO_2) in ambulatory, non-ambulatory and transport environments

Indications for Use

The Propaq LT 802 series monitors are highly portable devices intended to be used by clinicians and medically qualified personnel for single or multi-parameter vital signs

monitoring of ambulatory and non-ambulatory neonate, pediatric and adult patients. These monitors are indicated for ECG, noninvasive blood pressure (NIBP), respiration and SpO_2. The most likely locations for patients to be monitored by this device are hospital general medical-surgical, telemetry, and intermediate care floors, hospital emergency departments, transport, emergency medical services and other healthcare applications. The monitors may be used as standalone devices or as devices networked to an Acuity® central station through wireless communication over Welch Allyn's FlexNet™ network.

This device is available for sale only upon the order of a physician or licensed health care professional.

Summary of Performance Testing

The Welch Allyn Propaq LT 802 Series vital signs monitor will be tested in accordance with the Test Plan / Report, PN 831-0728-XX included with the submission using production equivalent units prior to release to market.

A risk analysis PN 831-0692-XX identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Welch Allyn Protocol's product development procedure. Welch Allyn Protocol's Quality System conforms to 21CFR820 and is certified by TÜV Product Service to ISO 9001, EN 46001 and ISO 13485.

Conclusions

As documented and stated above, Welch Allyn Protocol's conclusion is that the Welch Allyn Propaq LT 802 Series monitors are safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the earlier identified predicate devices.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Welch Allyn, Inc.
c/o Mr. David Klementowski
Corporate Regulatory Affairs Manager
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K033378
Trade Name: Propaq LT Vital Signs Monitor, Model 802 Series
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: MWI
Dated: January 27, 2004
Received: January 28, 2004

Dear Mr. Allyn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033378

Device Name: Propaq LT vital signs monitor, model 802 series

Indications For Use:

The Propaq LT 802 series monitors are highly portable devices intended to be used by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of ambulatory and non-ambulatory neonate, pediatric and adult patients. These monitors are indicated for ECG, noninvasive blood pressure (NIBP), respiration and SpO_2. The most likely locations for patients to be monitored by this device are hospital general medical-surgical, telemetry, and intermediate care floors, hospital emergency departments, transport, emergency medical services and other healthcare applications. The monitors may be used as standalone devices or as devices networked to an Acuity [R] central station through wireless communication over Welch Allyn's FlexNet[TM] network.

This device is available for sale only upon the order of a physician or licensed health care professional.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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